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<u>L10</u>	L9 and 13	2	<u>L10</u>
<u>L9</u>	L2 and flexible container	53	<u>L9</u>
<u>L8</u>	16 and flexible container	0	<u>L8</u>
<u>L7</u>	L6 and "perfusion filter"	0	<u>L7</u>
<u>L6</u>	L3 and perfusion	10	<u>L6</u>
<u>L5</u>	L3 and fabric	0	<u>L5</u>
<u>L4</u>	L3 and isolator	0	<u>L4</u>
<u>L3</u>	L2 and septum	19	<u>L3</u>
<u>L2</u>	L1 and microporous	242	<u>L2</u>
<u>L1</u>	flexible same container and filter	5258	<u>L1</u>

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L3: Entry 16 of 19

File: USPT

Aug 9, 1994

DOCUMENT-IDENTIFIER: US 5336180 A
TITLE: Closed drug delivery system

Brief Summary Text (4):

Medicament delivering systems that can separately store and then controllably intermix a selected medicament with a diluent for infusion into a patient at a controlled rate have come into wide use. In the prior art systems the diluent is generally packaged in flexible plastic containers having administration ports for connection to an administration set which delivers the container contents from the container to the patient. The drug is often packaged in a separate, closed container and is mixed with the diluent shortly before infusion of the medicament in the patient.

Brief Summary Text (7):

Several types of closed drug delivery systems are presently in use. These systems typically comprise a flexible container such as a plastic bag to which a drug vial can be coupled. The flexible container usually contains a liquid diluent and often includes a frangible member that allows fluid passage only when broken. When the drug vial is coupled with the flexible container, the stopper of the drug vial is pierced and the frangible member ruptured so as to allow sterile communication between the drug vial and the liquid diluent contents of the flexible container. Mixing of the drug with the diluent is accomplished by manipulating the flexible container. Exemplary of prior art systems of the aforementioned character are those disclosed in U.S. Pat. No. 4,583,971 issued to Bocquet, et al. and in U.S. Pat. No. 4,606,734 issued to Larkin.

Brief Summary Text (9):

Another very successful prior art, dual container system is described in U.S. Pat. Nos. 4,614,267 issued to Larkin and 4,614,515 issued to Tripp and Larkin. In this system, a flexible diluent container includes a tubular port which provides means for securing thereto a stoppered medicament vial as well as a stopper removal means. The stopper removal means includes an engagement element, or extractor, which is attached to a removable cover and seals the inner end of the port. In use, as the vial is advanced into the tubular port, the vial stopper moves into engagement with the extractor which grips the stopper enabling it to be pulled from the vial as the cover is pulled from the port. Once the stopper has been removed from the vial, the contents of the vial can be dumped into the diluent in the bag and mixed therewith through manipulation of the bag.

Brief Summary Text (11):

The apparatus of the present invention overcomes the drawbacks of the prior art by totally eliminating the need for a flexible bag, the cumbersome manipulative mixing of the medicaments using the flexible bag and the undesirable gravity infusion method which is typically followed when the flexible bag is used. As will be described in the paragraphs which follow, the apparatus of the present invention makes use of recently developed gas permeable elastomeric films and similar materials, which, in cooperation with a plate-like base define a fluid chamber that initially contains the first component, such as a diluent. Adjacent the base and in communication with the fluid chamber is a sterile coupling means for operably interconnecting a container such as a drug vial containing the second component. To

enable controlled, sterile intermixing of the first and second components, the apparatus includes flow control means for controlling the flow of fluid through internal passageways which interconnect the fluid chamber and the drug vial.

Brief Summary Text (26):

Yet another object of the invention is to provide an apparatus of the class described in which a thin, planar filter element is disposed within the fluid chamber for filtering the reservoir outflow to the patient.

Detailed Description Text (26):

With respect to the structural filter 40, many types of porous plastic materials can be used. In certain embodiments of the invention, this component can be produced from one of several polymer groups. The plastic structure of this component typically contains an intricate network of open celled omni directional pores. The pores can be made in average sizes for 0.8 micron to 2,000 micron and, gives the porous plastic a unique combination of venting and structural strength. Further, the material is strong, lightweight, has a high degree of chemical resistance and, depending on the particular configuration of the apparatus, can be flexible. The degree of hardness can range from soft, resilient or rigid, and depending on the specific micro diameter range desired, the following polymers can be employed: Polypropylene(PP), Ultra high molecular weight polyethylene (UHMW PE), High density polyethylene (HDPE), Polyvinylidene Fluoride (PVDF), Ethylene-vinyl acetate (EVA), Styrene Acrylonitrile (SAN), Polytetrafluoroethylene (PTFF).

Detailed Description Text (50):

Forming an important aspect of this latest form of the apparatus of the invention is the provision of filter means which is disposed internally of chamber 432 for filtering fluids flowing from chamber 432 into fluid passageways 412 formed in base member 406. The filter means also functions as an interfacial bubble trap. In the embodiment of the invention here shown, the filter means is provided in the form of a thin, micro-porous film, laminate or composite membrane 434 which is fitted over the front surface 408 of base 406 in the manner shown in FIG. 27. Front surface 408 provides support means for filter 434. Membrane 434 can be constructed from a wide variety of filtering materials of a character well understood by those skilled in the art, including Cellouous Acetate, Polytetraflouroethylene, Polypropylene, Polyvinylidene Flouride and Polyurethane/Polyethylene Composite.

Detailed Description Text (53):

Base assembly 404 also includes an outlet or delivery port 448, which is normally closed, by a removable cover member 450. Outlet port 448 is in communication with fluid passageway 414 and an outlet 417 via a conduit 452 (FIG. 28). Outlet port 448 and passageway 452 are also in communication with a transversely extending passageway 454 formed in base 406 which terminates at its outer end in an opening 456 (FIG. 28). Receivable within opening 456 (FIG. 23) is an outlet flow control means shown here as a shut-off and fluid metering means of the character previously discussed herein and identified in FIGS. 2 and 6 by the numeral 63. In the manner previously described, needle valve means 63 functions to either substantially close or to controllably restrict the flow of fluid outwardly of the device through passageway 414 and outlet port 448. As seen in FIG. 28, passageway 454 is internally threaded to threadably receive external threads 458 formed on a stem 460. With this construction, by rotating a control knob 462 attached to stem 460, the valve member can be moved axially of passageway 454 to controllably move tapered portion 464 provided on stem 460 proximate its inner end relative to passageway 454 and into engagement with a valve seat 464a provided in base 406 (FIG. 28). An O-ring 463 is provided to seal stem 460 relative to passageway 454. Alternatively to, or in conjunction with, the needle valve, passageway 452 can be initially sealed by an internal structural septum 465 (FIG. 23) which can be pierced by an I-V administration set piercing spike. This type of recipient port a septum structure is well known in the art.

Detailed Description Text (54):

Turning to FIGS. 23 and 29, the construction of the container assembly 300 can be seen to be of similar construction to that shown in FIGS. 17 through 22. The container assembly, the details of construction of which will not be repeated here, is receivable within cylindrical housing portion 400 and the plunger 86 is initially mated with the coupling member 112 in the manner previously described (See also FIGS. 32 and 33). In this latest form of the invention, cylindrical portion 400 is integrally connected to the back or concave surface 410 of base member 406 by means of a connector flange 470 (FIG. 23). Portion 400 also includes a transversing extending base wall 471 having a socket 473 which supports coupling member 112 in a manner best seen in FIG. 30. Base wall 471 is provided with a passageway 477 which communicates with passageway 124 of coupling member 114 and with passageway 414 of base 402 via port 415. Similarly, an outlet passageway housing 472 and a needle valve housing 474 extend angularly outwardly from back surface 410 (FIGS. 26 and 28). It is to be noted that the front surface 408 of base member 406 is provided with an upstanding mounting boss 475 which surrounds port 415 and to which filter 434 is bonded. Filter 434 is provided with an aperture 434a which peripherally receives boss 475 so that fluid can flow freely through port 415 between channel 414 and chamber 432. (FIG. 25) .

Detailed Description Text (58):

Continued movement of the drug vial assembly into the final position shown in FIG. 31 causes the reconstituted mixture to be substantially transferred back into chamber 432 of the infusion device via passageways 94, 103, 126, 124, 477 and 414 and through port 415 for later controlled infusion of the reconstituted drug active medicament into the patient via the filter 434 and the multiplicity of fluid collection passageways 412, into passageway 414 through port 417 and outwardly of the device through passageway 452 and outlet 448. As previously discussed, the rate of flow fluid through outlet 448 is controlled by the needle valve means 63.

Detailed Description Text (61):

Turning first to FIGS. 34 and 35, the base assembly can be seen to be quite similar to that shown in FIG. 25 having a curved base member 406 provided with a multiplicity of flow micro-channels 412 which communicate with a central passageway 414 having spaced-apart portions 413 and 416. Side portion 418 having apertures 420 are as previously described. The apparatus also includes a distendable elastic membrane 430 and filter means 434 which function as before. Turning to FIG. 36, the drug vial or container assembly 502 of this form of the invention, includes second flow control means for controlling the flow fluid into and out of an internal chamber 509 of a vial 510 which contains the medicament M. The second flow control means of this form of the invention is identical in construction and operation to that previously described and includes a lower durometer plunger 86 which is substantially sealably receivable within vial 510. Plunger 86 also includes connector means, shown as threads 86b, for interconnection with the coupling means of the apparatus. As before, valve assembly 88 controls fluid flow through flow passageways formed within plunger 86 and is operated by operating means of the character previously described.

Detailed Description Text (65):

In all forms of the invention previously described, the plunger of the container valve is preferably constructed from a rubber or silicon material. The valve member which reciprocates within the plunger is preferably constructed of higher durometer rubber or silicon, or from glass or plastic materials such as polypropylene, polycarbonate, polystyrene, ABS, PTFE or high density teflon or nylon. Similarly, valve member 137 is preferably constructed from silicon rubber, rubber, flexible PVC, polyurethane, PTFE, or fluorsilicon elastomers.

Detailed Description Text (67):

In this latest form of the invention, cylindrical portion 600 is integrally connected to the back or concave surface 410 of the base member by means of a

connector flanges 470 (FIG. 23). Portion 600 also includes a transversing extending base wall 607 having a socket 609 which supports a coupling member 612 in a manner best seen in FIG. 40. Base 406 is provided with longitudinally extending passageways 614 and 616. Passageway 614 communicates with storage reservoir 432 and with port 415. Passageway 616 communicates with the outlet port of the device formed in outlet passageway housing 472. Similarly, a needle valve housing 474 of the character previously described extends angularly outwardly from back surface 410 (See also FIGS. 26 and 28). It is to be noted that the front surface of the base member is provided with crossing micro flow channels 412 and with an upstanding mounting boss 475 which surrounds port 415 and to which a filter membrane 434 is bonded (FIG. 39). Filter means and micro flow channels 412 function in the same manner to accomplish the same result as previously described herein.

Detailed Description Text (73):

With valve member 642 in the position shown in FIG. 45, the mixed solution, or beneficial agent, will continue to flow under pressure through passageways 640, into passageways 668 formed in coupling member 612, into annular collector passageway 670 (FIG. 47) into passageway 672 formed in cylindrical portion 600 and thence to the outlet port via passageway 452. A filter member 674 is provided within medicament chambers 624 to filter out particulate matter prior to the dispensing of the reformulate dbeneficial agent from the device.

Detailed Description Text (80):

Referring particularly to FIG. 55, it is to be noted that so long as valve member 742 is in the position there shown, flange 741, including protuberances 741a as provided thereon, will block fluid flow through passageways 740 of plunger 736. However, as previously mentioned, clockwise rotation of the vial assembly 720 within the overpackage 726 will cause valve member 742 will move to the right due to the urging of check valve 746. So long as member 742 is in the position shown in FIG. 56, The mixed solution, or beneficial agent, will continue to flow under pressure in a reverse direction toward reservoir 432 through passageways 740, into passageways 668 formed in coupling member 612, into annular passageway 670 (FIG. 49) into passageway 672 formed in cylindrical portion 600 and thence to reservoir 432. As before a filter member 774 is provided within medicament chambers 724 to filter out particulate matter prior to the beneficial agent being dispensed from the device.

Detailed Description Text (93):

The adding means of the invention can take several different forms such as those illustrated in FIG. 66. However, in its preferred form, the adding means comprises a cylindrically shaped, microporous polymeric functional support structure which is disposed within the mixing chamber of the container assembly and to which various additives, including beneficial agents such as drugs, biologically active materials, and chemical elements and compounds can be releasably connected. These additives are carried by the structure in a manner such that, as the liquid, such as a diluent, reagent, or other aqueous solvent flows around, about and through the support assembly in the manner shown by the arrows in FIG. 64, the additives will be presented to the liquid flow and efficiently released and added to the liquid as it flows through the chamber which houses the adding means.

Detailed Description Text (97):

As best seen in FIGS. 63 and 64, in this latest form of the invention, cylindrical portion 800 is integrally connected to the back or concave surface 410 of the base member by means of connector flanges 470 (FIG. 23). Portion 800 also includes a transversing extending base wall 807 having a socket 809 which supports a coupling member 812 in a manner best seen in FIGS. 40 and 64. Base 806 is provided with longitudinally extending passageways 814 and 816. Passageway 814 communicates with storage reservoir 832 and with port 815. Passageway 816 communicates with the outlet port of the device formed in the outlet passageway housing 872. This

passageway can also be used to aseptically prefill the reservoir during the manufacturing process. Similarly, a needle valve housing 874 of the character previously described extends angularly outwardly from back surface 410 (See also FIGS. 26 and 28) and carries the second flow control means of the invention for controlling the flow of fluid through the fluid outlet of the base assembly. It is to be noted that the front surface of the base member is provided with crossing micro flow channels 812 and with an upstanding mounting boss 875 which surrounds port 815 to which a filter membrane 834 is bonded (FIG. 63). Filter means and micro-flow channels 812 function in the same manner to accomplish the same result as previously described herein.

Detailed Description Text (104):

In addition to the additive presentation means previously discussed, a polymer can also be used as the carrier or support for the additive. Three classes of polymeric supports can be used, namely polymeric reagents, polymeric catalysts and polymeric substrates. A discussion of polymers as carriers or supports is contained in Principles of Polymerization, Second Edition by George Odian. Microporous polymers usable as carriers are also fully described in U.S. Pat. No. 4,519,909 issued to Castro.

Detailed Description Text (109):

The numeral 886 of FIG. 66 identifies yet another form of the adding means of the invention. In this form of the invention a generally cylindrically shaped functional support serves as an affinity attachment for attachment and subsequent release of the additive. Support 886 has an axial fluid passageway 887 and is formed from a multiplicity of microporous polymers presenting a multiplicity of reactive sites over a wide area for species immobilization.

Detailed Description Text (135):

As seen in FIG. 67, a needle valve housing 874 of the character previously described extends angularly outwardly from back surface 410 (See also FIGS. 26 and 28) Needle valve 874a is carried by housing 874 and functions in the manner previously described, with cap 874b securing the adjustment end of the valve. It is to be noted that the front surface of the base member is also provided with crossing micro flow channels 812 which communicate with port 815 to which a filter membrane 834 is bonded. Filter means and micro-flow channels 812 function in the same manner to accomplish the same result as previously described herein.

Detailed Description Text (147):

Similarly, a needle valve housing 874 of the character previously described which houses a needle valve assembly 874a extends angularly outwardly from back surface 410 (See also FIGS. 26 and 28). Valve 874a comprises the second flow control means of the invention for controlling fluid flow outwardly of the device. It is to be noted that the front surface of the base member is also provided with crossing micro flow channels 812 which communicate with port 815 to which a filter membrane 834 is bonded. Filter means and micro-flow channels 812 function in the same manner to accomplish the same result as previously described herein.

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<u>L9</u>	L2 and flexible container	53	<u>L9</u>
<u>L8</u>	l6 and flexible container	0	<u>L8</u>
<u>L7</u>	L6 and "perfusion filter"	0	<u>L7</u>
<u>L6</u>	L3 and perfusion	10	<u>L6</u>
<u>L5</u>	L3 and fabric	0	<u>L5</u>
<u>L4</u>	L3 and isolator	0	<u>L4</u>
<u>L3</u>	L2 and septum	19	<u>L3</u>
<u>L2</u>	L1 and microporous	242	<u>L2</u>
<u>L1</u>	flexible same container and filter	5258	<u>L1</u>

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☐ 1. Document ID: US 5119588 A

L19: Entry 1 of 1

File: USPT

Jun 9, 1992

US-PAT-NO: 5119588

DOCUMENT-IDENTIFIER: US 5119588 A

**** See image for Certificate of Correction ****

TITLE: Method and apparatus for culturing autotrophic plants from heterotrophic plant material

DATE-ISSUED: June 9, 1992

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Timmis; Roger	Olympia	WA		
Kreitinger; Mary E.	Fall City	WA		
Yancey; Michael J.	Puyallup	WA		

US-CL-CURRENT: 47/58.1R; 435/297.5, 435/305.3, 435/422, 435/430, 435/430.1, 47/73, 47/84, 47/85

Full	Title	Citation	Front	Review	Classification	Date	Reference			Claims	INDEX	Drawings
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	10/353871	08/23/2004	71	e	e	210	652.000	-1	-	SPEC
	10/406807	08/16/2004	71	e	e	210	650.000	-1	-	-
	10/327564	08/07/2004	71	e	e	210	500.410	-1	-	-
	10/275210	08/25/2004	71	e	e	210	321.840	-1	-	-
	10/275129	07/13/2004	71	e	e	210	500.210	1+	-	-
	10/265188	07/14/2004	71	e	e	210	644.000	1+	-	-
	10/232098	07/07/2004	71	e	e	210	500.430	1+	-	-
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	10/216242	07/29/2004	71	e	e	210	500.210	1	-	-
	10/203106	07/06/2004	71	e	e	210	321.600	1+	-	-
	10/156894	07/24/2004	71	e	e	210	500.210	1	-	-
	10/140445	07/26/2004	71	e	e	210	650.000	1	-	-
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	10/079360	08/17/2004	71	e	e	210	767.000	-1	-	-
	09/909488	09/02/2004	71	e	e	210	651.000	-1	-	-
	09/884215	07/28/2004	71	e	e	210	500.100	1	-	-
	09/698378	07/21/2004	71	e	e	210	321.600	1	-	-
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L19: Entry 1 of 1

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Timmis; Roger	Olympia	WA		
Kreitinger; Mary E.	Fall City	WA		
Yancey; Michael J.	Puyallup	WA		

US-CL-CURRENT: 47/58.1R; 435/297.5, 435/305.3, 435/422, 435/430, 435/430.1, 47/73, 47/84, 47/85

Full	Title	Citation	Front	Review	Classification	Date	Reference			Claims	KWIC	Draw. De
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